**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| **IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION**<br><br>This document relates to:<br>*The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*<br>Case No. 18-op-45090<br><br>and<br><br>*The County of Cuyahoga v. Purdue Pharma L.P., et al.*<br>Case No. 1:18-op-45004 | MDL No. 2804<br><br>Hon. Dan A. Polster |

**REPLY IN SUPPORT OF DEFENDANTS' DAUBERT MOTION TO EXCLUDE THE OPINIONS OF SETH B. WHITELAW**

## I. INTRODUCTION

Defendants' *Daubert* motion identifies two fatal problems with Plaintiffs' purported DEA suspicious order monitoring expert Seth Whitelaw: (1) he has no relevant experience with controlled substances, the Controlled Substances Act ("CSA"), or the Drug Enforcement Agency ("DEA"), and thus is unqualified to testify as an expert on DEA suspicious order monitoring programs; and (2) Whitelaw's methodology is unreliable because the undisputed record confirms that the Federal Sentencing Guidelines—the foundation of his analysis—are *not* used by those in the field or by DEA to develop or evaluate DEA suspicious order monitoring programs. Plaintiffs do not dispute, and fail to even address, DEA's testimony that the Federal Sentencing Guidelines are not used to evaluate suspicious order monitoring programs.

Recognizing these deficiencies, Plaintiffs recast Whitelaw's opinions as "a holistic assessment of Defendants' compliance programs, of which their anti-diversion efforts were a part." Opp. at 1 (Dkt. 2189/2221). But Whitelaw's opinions are not general compliance opinions. His opinions specifically analyze certain Defendants' DEA suspicious order monitoring programs. In over 180 pages of "Individual Company Reviews" in his report, Whitelaw analyzes *only* the DEA suspicious order monitoring systems used by each company. For example, Whitelaw reports on McKesson's "three different SOM programs," Whitelaw Rpt. at 53 (Dkt. 2000-26), but offers *no* analysis of any other McKesson compliance program—not FDA, not SEC, not anything else. Nor does Whitelaw evaluate the general compliance programs of other Defendants in this litigation. *See, e.g.*, Whitelaw Tr. at 562:15-564:7; 713:6-714:3 (Dkt. 1972-7).

Plaintiffs' effort to recast Whitelaw's opinions as "a comprehensive examination of Defendants' compliance programs as a whole" is also flatly inconsistent with their use of his opinions in other contexts. Opp. at 3 (Dkt. 2189/2221). In Plaintiffs' Opposition to Defendants'

Motions for Summary Judgment on Proof of Causation, Plaintiffs offer Whitelaw as a purported expert in suspicious order monitoring programs, identifying Whitelaw as one of "Plaintiffs' SOMs experts" who "provide[s] opinions about deficiencies in Defendants' SOMs programs." Dkt. 2203 at 29.[1]

Whitelaw is unqualified; his opinions are unreliable; and—as a lawyer expert—he purports to opine on ultimate legal issues in this case. His opinions should be excluded.

## II. ARGUMENT

### A. Plaintiffs' Opposition Confirms Whitelaw is Unqualified.

Whitelaw's own curriculum vitae and deposition testimony belie Plaintiffs' claim that Whitelaw "possesses specific expertise relevant to anti-diversion efforts." Opp. at 4 (Dkt. 2189/2221). There is no dispute that Whitelaw is an attorney with no DEA experience, no experience with the wholesale distribution or manufacture of opioids, and no experience with DEA suspicious order monitoring programs for controlled substances. Whitelaw Rpt. at 279-82 (Dkt. 2000-26); Whitelaw Tr. at 86:4-7; 63:16-20; 760:12-761:20 (Dkt. 1972-6, 1972-7).

Whitelaw's own words highlight his inexperience with DEA suspicious order monitoring programs for controlled substances. At deposition, he was unable to define the term "diversion" without looking it up in his report. Whitelaw Tr. at 500:10-501:18 (Dkt. 1972-6). This alone should disqualify him, because an expert's qualifications must "provide a foundation for the

[1] Plaintiffs further describe Whitelaw as reviewing "Defendants' shipments of orders that were, or should have been, flagged as suspicious, the total volume of shipments, and at particular downstream pharmacy customers from which diversion was likely, but to whom Defendants continued to ship large quantities of opioids throughout the opioid epidemic." Dkt. 2203 at 29. Such an evaluation goes to the heart of suspicious order monitoring. The disingenuousness of Plaintiffs' Opposition's portrayal of Whitelaw as anything other than a purported expert in suspicious order monitoring is belied by Plaintiffs' own briefing filed the same day.

witness to answer a specific question." *Newell Rubbermaid, Inc. v. Raymond Corp.*, No. 08-CV-2632, 2010 WL 2643417, at *3 (N.D. Ohio July 1, 2010), *aff'd* 676 F.3d 521 (6th Cir. 2012).

In an effort to manufacture qualifications for Whitelaw, Plaintiffs identify three purported examples of Whitelaw's "specific expertise relevant to anti-diversion efforts." Opp. at 4 (Dkt. 2189/2221).

First, Plaintiffs identify a proposal Whitelaw submitted to distributor Henry Schein while working at Deloitte. In this unsuccessful pitch (which was not, as Plaintiffs imply, an actual work assignment), the presentation identified team members *other* than Whitelaw as the "Subject Matter Advisors" for the project. Opp. Ex. 2 at 8 (Dkt. 2222-1).[2] Whitelaw is identified only as the "Engagement Lead." *Id*. In any event, Henry Schein did not award Deloitte the contract, so Whitelaw's employment at Deloitte provided no relevant experience on the subject. Whitelaw identifies no other prior work that even touched upon DEA suspicious order monitoring programs, acknowledging at deposition that he has never designed, operated, or audited such a program. Whitelaw Tr. at 66:15-20; 63:16-20; 760:12-761:20 (Dkt. 1972-6, 1972-7).

Second, Plaintiffs point to Whitelaw's purported experience designing "sample accountability [Prescription Drug Marketing Act] programs" as "substantially equivalent to anti-diversion programs for controlled substances." Opp. at 4 (Dkt. 2189/2221); Whitelaw Tr. at 63:16-64:11 (Dkt. 1972-6). But Whitelaw testified at deposition that PDMA programs are only governed by the CSA and its corresponding regulations "if you're dropping controlled substances samples." Whitelaw Tr. at 64:12-65:20 (Dkt. 1972-6). Whitelaw further testified that

[2] Bill Greenrose, one of the "Subject Matter Advisors," had 33 years of experience with DEA compliance efforts for pharmaceutical companies. Opp. Ex. 2 at 16 (Dkt. 2222-1). George Seafin, another "Subject Matter Advisor," also had DEA regulatory compliance experience. Opp. Ex. 2 at 15 (Dkt. 2222-1).

"[i]f you're not dropping controlled substances samples, the answer is no, [the CSA] would not apply." *Id.* Whitelaw admitted he never designed a program that dropped controlled substances samples, although he had hoped for an opportunity to do so through the failed pitch to Henry Schein. Whitelaw Tr. at 65:21-66:13 (Dkt. 1972-6). Again, Whitelaw's purported experience is no experience at all.

Third, Plaintiffs point to Whitelaw's conversations with James Rafalski, another of Plaintiffs' suspicious order monitoring experts, as a "supplement" to Whitelaw's experience. Opp. at 4 (Dkt. 2189/2221). But, Rafalski testified "[he] really didn't see any connection between what [Whitelaw's] opinion was going to be and [his] opinion, but at the request of plaintiff counsels, [they] had a couple of discussions." Rafalski Tr. at 48:17-21 (Dkt. 1881-10). Merely speaking to another expert involved in the litigation is not sufficient to gain the "knowledge, skill, experience, training, or education" to qualify as an expert. *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 816 F. Supp. 2d 442, 450 (W.D. Ky. 2011).

The decision in *Rheinfrank v. Abbott Labs., Inc.*, No. 13-cv-144, 2015 WL 13022172 (S.D. Ohio Oct. 2, 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017), which Plaintiffs cite, actually supports Defendants' motion here. There, the court considered the parties' *Daubert* motions against several expert witnesses. As Plaintiffs' Opposition correctly observes, the court qualified one expert—who possessed 25 years of FDA experience and served on a relevant FDA labeling task force—to testify about compliance with FDA requirements concerning drug labeling. *Rheinfrank*, 2015 WL 13022172, at *14. Plaintiffs ignore the *Rheinfrank* court's evaluation of a second expert, who the court found was *not* qualified to testify as an expert in FDA labeling regulations because he had never consulted with FDA about drug labels. *Id.* at *6. The court explained that the second expert "is not an expert in FDA regulations" and "lacks the requisite

expertise to opine as to the regulatory aspects of the case." *Id*. As with the second expert in *Rheinfrank*, Whitelaw lacks the experience to serve as an expert on suspicious order monitoring.

**B. Plaintiffs' Opposition Confirms that Whitelaw's Analysis Is Unreliable.**

**1. DEA Does Not Apply the Federal Sentencing Guidelines to Suspicious Order Monitoring Programs for Controlled Substances.**

Plaintiffs do not dispute that DEA does not apply the Federal Sentencing Guidelines to suspicious order monitoring programs for controlled substances. Nor could they. DEA testified that DEA does not use the Federal Sentencing Guidelines to evaluate registrants' suspicious order monitoring programs and that diversion investigators are not trained to use the Federal Sentencing Guidelines to evaluate suspicious order monitoring programs. Prevoznik Tr. at 1202:2-20 (Dkt. 1881-12).

Plaintiffs fail to even address DEA's testimony. Instead, Plaintiffs rely on Whitelaw's own testimony to support his methodology and reliance on the Federal Sentencing Guidelines. Opp. at 5-6 (Dkt. 2189/2221). It is well established, however, that an expert's methodologies are not generally accepted in a field simply because he says they are. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 254-55 (6th Cir. 2001) (same). There is no general acceptance here—and the agency charged with enforcing the CSA rejected using the Federal Sentencing Guidelines to evaluate suspicious order monitoring programs.

Plaintiffs then point to various industry documents in an attempt to show that certain Defendants use the Federal Sentencing Guidelines in their compliance programs. Opp. at 6-8 (Dkt. 2189/2221). Not one of the cited documents, however, identifies the Federal Sentencing Guidelines as the basis for DEA suspicious order monitoring programs. Not one of the

documents shows a Defendant using the Federal Sentencing Guidelines to develop a DEA suspicious order monitoring program or to evaluate suspicious orders and pharmacy customers. Plaintiffs then point to general compliance publications as further support that industry uses the Federal Sentencing Guidelines. Opp. at 8-9 (Dkt. 2189/2221). But none of the referenced publications concern DEA suspicious order monitoring programs or controlled substances.

Plaintiffs' final attempt to justify using the Federal Sentencing Guidelines as the basis for DEA suspicious order monitoring programs is inventive, but falls flat. Plaintiffs contend that certain topic headings found in McKesson's audit reports and settlement documents—such as "due diligence," "written standards," "non-retaliation policies" and "ethics hotlines"—can creatively be read to "mirror" the Federal Sentencing Guidelines. Opp. at 9-10 (Dkt. 2189/2221). But the use of common terms such as "due diligence" and "ethics hotline" without more does not qualify as "evidence" that any Defendant actually relied on the Federal Sentencing Guidelines or guidance from the Office of the Inspector General at the Department of Health and Human Services on certain healthcare industries—nor that any Defendant should have done so.

**2. Whitelaw's Model Is Created for Litigation and Should Be Excluded.**

Defendants do not dispute that general maturity models existed prior to this litigation. As Plaintiffs point out, for example, Novo Nordisk used such a model to "track societal learning on some of its core business issues." Opp. Ex. 18 at 4-6 (Dkt. 2224-2). But Whitelaw did not use a general maturity model. Instead, Whitelaw "derived" a *new* model that combines elements from a general maturity model with his own "attributes" for a "good anti-diversion program." Whitelaw Tr. at 246:3-17 (Dkt. 1972-6); Whitelaw Rpt. at 28-42 (Dkt. 2000-26). Whitelaw uses his *new* model to evaluate certain Defendants' DEA suspicious order monitoring programs.

Before this litigation, no one had ever used a general maturity model, much less

Whitelaw's new derivation, to evaluate DEA suspicious order monitoring programs. At deposition, Whitelaw admitted that he had never used his model to evaluate DEA suspicious order monitoring programs prior to this litigation. Whitelaw Tr. at 715:8-19 (Dkt. 1972-7). Whitelaw was also unable to identify anyone who had applied similar maturity models to evaluate DEA suspicious order monitoring programs. Whitelaw Tr. at 245:12-18 (Dkt. 1972-6). Recognizing this deficiency, Plaintiffs refer to a Deloitte model purportedly used by Cardinal in 2009. Opp. at 12 (Dkt. 2189/2221). But that model evaluated IT systems, not DEA suspicious order monitoring programs. Opp. Ex. 16 at -295-296 (Dkt. 2224). Whitelaw's methodology was created for the purpose of litigation, is unreliable, and should be excluded.

**C. Attorney Whitelaw Improperly Opines on an Ultimate Legal Issue.**

As Plaintiffs try to resuscitate Whitelaw and reframe his opinions as a general "assessment of Defendants' compliance programs," they now contend that "Whitelaw does not opine on whether Defendants have acted contrary to any specific laws or regulations, including the CSA." Opp. at 13 (Dkt. 2189/2221). Whitelaw's report and testimony show otherwise.

Relying on Whitelaw's legal background, Plaintiffs asked him to evaluate whether certain Defendants' DEA suspicious order monitoring programs were effective and satisfied the legal requirements. Whitelaw Rpt. at 2-3 (Dkt. 2000-26). Whitelaw opines that certain programs do not comply with the requirements of the CSA and corresponding regulations. For example, Whitelaw opines:

- "[McKesson's] Section 55 . . . does not meet the basic DEA requirements for a SOM Program." Whitelaw Rpt. at 72 (Dkt. 2000-26).
- "Cardinal's early controlled substances program was not compliant with DEA regulatory requirements." Whitelaw Rpt. at 109 (Dkt. 2000-26).
- "Poor program design and inconsistent application of the standards that were developed exacerbated the deficiencies in AmerisourceBergen's controlled substances program

> leading to a predictable outcome that ABC's program credibly failed to identify, report and stop suspicious orders." Whitelaw Rpt. at 128 (Dkt. 2000-26).

These are *legal* opinions.

Plaintiffs cite to *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994), for the proposition that, while an expert may not testify to a legal conclusion, an expert may testify about factual issues that suggest the answer to the ultimate legal issue. Opp. at 13 (Dkt. 2189/2221). *Berry*'s discussion of this point illustrates why Whitelaw's opinions fall on the wrong side of the dividing line: the Sixth Circuit "would not allow a fingerprint expert in a criminal case to opine that a defendant was guilty (a legal conclusion), even though [the Sixth Circuit] would allow him to opine that the defendant's fingerprint was the only one on the murder weapon (a fact)." *Berry*, 25 F.3d at 1353. Applying this analogy, *Berry* excluded the testimony of an expert who opined that lax disciplinary policies of the Detroit Police Department indicated the City was deliberately indifferent to the welfare of its citizens—the ultimate legal conclusion in the case. *Id*. Similarly, Whitelaw concludes that Defendants' DEA suspicious order monitoring programs "do[] not meet the basic DEA requirements" and "[are] not compliant with DEA regulatory requirements"—ultimate legal issues in this case. The law is clear: an expert witness may not testify as to the ultimate legal issues in the case. *United States v. Geiger*, 303 F. App'x 327, 331 (6th Cir. 2008).

## III. CONCLUSION

For the foregoing reasons, the Court should exclude the opinions of Whitelaw.

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Respectfully submitted,

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[3] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

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**CERTIFICATE OF SERVICE**

I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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